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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,726	09/30/2003	Diane K. Burnside	23,369-155	4006

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PATENT DEPARTMENT
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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,726	BURNSIDE ET AL.	
	Examiner	Art Unit	
	Bruce E Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-76* is/are pending in the application.

4a) Of the above claim(s) *57 and 66-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-58 and 60-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/20/04; 7/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 66-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/05/2005.

Claim 57 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/05/2005.

Information Disclosure Statement

The information disclosure statement filed 7/26/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. And/or the information disclosure statement filed 7/26/04 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

The Examiner notes the considered art is listed on the first two pages of U.S. Patent 6,626,939 and, these, have been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

All claims are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all claims of U.S. Patent No. 6,626,939. Although the conflicting claims are not identical, they are not patentably distinct from each other claiming the identical stent-graft. The current application more broadly claims the patented claims comprising a structural layer which is tubular (tubular structure) which is bioabsorbable further having a compliant graft.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 36-38, 43-45, 48-49, 52-54, 63-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Fontaine et al (5,527,354).

Fontaine et al teaches a stent-graft comprising:

a structural layer 2 comprising a bioabsorbable (see column 7, 62-65 teaching Vicryl (PGA)), radially compressible and radially expandable annealed tubular body having open ends and a sidewall structure having openings therethrough; and

a compliant graft layer cooperating with the structural layer to form a stent-graft (see column 7, lines 31 et seq.) implantable at a treatment site in a body lumen, wherein the compliant graft layer tends to conform to the tubular body ms the tubular body radially expands and contracts;

wherein the structural layer is radially expandable when deployed at the treatment site and thereby is adapted to fix the stent-graft at the treatment site and maintain patency of the body lumen;

characterized in that the structural layer further is adapted to be at least partially absorbed in-vivo following deployment, and the graft layer is adapted to remain at the treatment site while the tubular body is so absorbed.

Claims 36-40, 42, 44-58, 60-63, and 65 are rejected under 35 U.S.C. 102(b) as being **clearly anticipated** by Thompson et al (5,957,974).

Referring to all figures, specifically figure 13, Thompson et al teaches a stent-graft comprising:

a structural layer 106, 110 comprising a bioabsorbable (see 13:63-64), radially compressible and radially expandable annealed braided tubular body having open ends and a sidewall structure having openings therethrough; and

a compliant graft layer 108 cooperating with the structural layer to form a stent-graft implantable at a treatment site in a body lumen, wherein the compliant graft layer tends to conform to the tubular body ms the tubular body radially expands and contracts;

wherein the structural layer is radially expandable when deployed at the treatment site and thereby is adapted to fix the stent-graft at the treatment site and maintain patency of the body lumen;

characterized in that the structural layer further is adapted to be at least partially absorbed in-vivo following deployment, and the graft layer is adapted to remain at the treatment site while the tubular body is so absorbed.

Regarding at least claims 40 and 42, see Example 3.

All other limitations are self-evident.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41, 43, 59 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al (5,957,974) in view of Stinson (6,245,103).

Thompson et al discloses stent-graft as described above, however, fails to teach the materials used for the bioabsorbable structural layer (strands 110). Stinson teaches a similar braided stent constructed of a bioabsorbable material such as PGA or PLA. It would have been obvious to one having ordinary skill in the art to have utilized the bioabsorbable materials taught by Stinson for the bioabsorbable material of Thompson et al for their well know biocompatibility with the body, etc.

Regarding the adhesive being bioabsorbable, it would have been obvious to one having ordinary skill in the art to utilized a bioabsorbable adhesive for that taught by

Thompson et al for their know biocompatibility with the body and to reduce foreign material in the body and allow for increased body ingrowth. Additionally, lacking any criticality in the specification, the use of a bioabsorbable adhesive fails to produce any advantage over that taught by Thompson et al and is therefore considered an obvious matter of design choice.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER